



[Billing Code 4140-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive Patent License: Development of a NANOG-based therapeutic for cancer

AGENCY: National Institutes of Health

ACTION: Notice.

SUMMARY: The National Cancer Institute, an institute of the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an exclusive patent license to practice the inventions embodied in the U.S. Patents and Patent Applications listed in the Summary Information section of this notice to Inova Health System located in Falls Church, VA.

DATES: Only written comments and/or applications for a license which are received by the National Cancer Institute's Technology Transfer Center on or before [INSERT DATE 15 DAYS FROM DATE OF PUBLICATION OF NOTICE IN THE FEDERAL REGISTER] will be considered.

ADDRESSES: Requests for copies of the patent application, inquiries, and comments relating to the contemplated exclusive license should be directed to: Kevin W. Chang, Ph.D., Senior Licensing and Patenting Manager, NCI Technology Transfer Center, 9609 Medical Center Drive, RM 1E530 MSC 9702, Bethesda, MD 20892-9702 (for business mail), Rockville, MD 20850-9702 Telephone: (240)-276-6910; Facsimile: (240)-276-5504 E-mail: changke@mail.nih.gov.

SUPPLEMENTARY INFORMATION:

Intellectual Property

United States Provisional Patent Application No. No. 61/420,214, filed December 6, 2010, entitled “Allele Specific shRNAs For NANOG, Pharmaceutical Composition Comprising The shRNA, And Its Method of Use to Treat Cancer” [HHS Reference No. E-294-2010/0-US-01]; International PCT Application No. PCT/US2011/063451, filed December 6, 2011, entitled “Pharmaceutical Composition Comprising NANOG shRNA, and Method of Using NANOG shRNA to Treat Cancer” [HHS Reference No. E-294-2010/0-PCT-02]; United States Patent No. 9,163,236, issued October 20, 2015, entitled “Pharmaceutical Composition Comprising NANOG shRNA, and Method of Using NANOG shRNA to Treat Cancer” [HHS Ref. No. E-294-2010/0-US-03]; and United States Patent Application No. 14/886,970 filed October 19, 2015, entitled, “Pharmaceutical Composition Comprising NANOG shRNA, and Method of Using NANOG shRNA to Treat Cancer” [HHS Ref. No. E-294-2010/0-US-04].

The patent rights in these inventions have been assigned and/or exclusively licensed to the government of the United States of America.

The prospective exclusive license territory may be worldwide and the field of use may be limited to the use of Licensed Patent Rights for the following: “Treatment or prevention of colorectal cancer in humans.”

The subject technologies are short hair-pin RNAs which inhibit NANOG or NANOGP8 for the treatment of cancer and viral vectors that encode the RNAs. The first generation of these vectors were non-replicating lentiviral based vectors that were introduced into cancer cells as a standard form of RNA inhibition, blocking the

expression of NANOG or NANOGP8 protein. The most current version of the subject technology utilizes conditionally replicating, oncolytic adenovirus vectors. These adenovirus-based vectors grow in cells that express NANOGP8 but not in cells that lack NANOGP8 or where the shRNA has inhibited NANOGP8 expression. The vectors have been constructed to directly kill tumors and to inhibit the NANOGs to block cancer stem cell function in the tumors.

This notice is made in accordance with 35 U.S.C. 209 and 37 CFR Part 404. The prospective exclusive license will be royalty bearing, and the prospective exclusive license may be granted unless within fifteen (15) days from the date of this published notice, the National Cancer Institute receives written evidence and argument that establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR Part 404.

Complete applications for a license in the prospective field of use that are filed in response to this notice will be treated as objections to the grant of the contemplated Exclusive Patent License Agreement. Comments and objections submitted to this notice will not be made available for public inspection and, to the extent permitted by law, will not be released under the *Freedom of Information Act*, 5 U.S.C. 552.

September 29, 2016

Dated

Richard U. Rodriguez, M.B.A.

Associate Director

Technology Transfer Center

National Cancer Institute

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